IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
SPARTANBURG DIVISION

Vanida Khautisen, as Personal Representative of the Estate of Khouanexay Bill Sivilay, PLAINTIFF, v. BHG Holdings, LLC, and BHG XXXVIII, LLC, DEFENDANTS.	C.A. No. 7:21-cv-03775-TMC **MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE PLAINTIFF'S EXPERT, DR. NATHAN STRAHL**

Defendants, by and through counsel, hereby move this Honorable Court for an Order excluding Plaintiff's expert, Dr. Nathan Strahl, as a witness in this case. As grounds for their Motion, Defendants provide the following:

FACTS

BHG XXXVIII, LLC ("BHG") is an opioid treatment medical facility licensed by the South Carolina Department of Health and Environmental Control ("DHEC") and accredited by The Joint Commission (i.e., the same body that accredits many of our state's hospitals). The Substance Abuse and Mental Health Services Administration ("SAMHSA"), an agency within the United States Department of Health and Human Services, requires that opioid treatment programs ("OTP") be accredited by a federally deemed accrediting body.[1] Accrediting bodies approved by SAMHSA include The Joint Commission, CARF International, the Counsel on Accreditation, etc.[2]

[1] See 42 CFR 8.11, Opioid Treatment Program Certification; 42 CFR 8.12, Federal Opioid Treatment Standards

[2] See https://www.samhsa.gov/medications-substance-use-disorders/become-accredited-opioid-treatment-program/approved-accreditation-bodies

OTPs provide medication-assisted treatment ("MAT") using a full agonist narcotic (i.e., Methadone) to treat individuals suffering from the catastrophic disease known as Opioid Use Disorder ("OUD"). Opioid agonists, like Methadone, activate the opioid receptors in the brain, preventing withdrawal and reducing cravings for opioids like heroin and prescription pain medications. Due to its weaker efficacy, the medication Buprenorphine (a partial agonist) is typically restricted to those with mild to moderate opioid dependence, whereas Methadone can be used with all levels of dependence and is usually reserved for those with the most severe levels of dependence.[3] Methadone used to treat those with an OUD can only be dispensed through a SAMHSA certified OTP, like BHG.[4]

According to the NIDA's 2014 publication "Principles of Drug Addiction Treatment: A Research-Based Guide (Third Edition),"

> Substance abuse costs our Nation over $600 billion annually and treatment can help reduce these costs. Drug addiction treatment has been shown to reduce associated health and social costs by far more than the cost of the treatment itself. Treatment is also much less expensive than its alternatives, such as incarcerating addicted persons. **For example, the average cost for 1 full year of methadone maintenance treatment is approximately $4,700 per patient [i.e., approximately $13 per day]**, whereas 1 full year of imprisonment costs approximately $24,000 per person. According to several conservative estimates, every dollar invested in addiction treatment programs yields a return of between $4 and $7 in reduced drug-related crime, criminal justice costs, and theft. When savings related to healthcare are included, total savings can exceed costs by a ratio of 12 to 1.[5]

[3] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3271614/#:~:text=Choosing%20between%20buprenorphine%20and%20methadone&text=However%2C%20the%20patient's%20degree%20of,with%20all%20levels%20of%20dependence.

[4] See https://www.samhsa.gov/medications-substance-use-disorders/medications-counseling-related-conditions/methadone

[5] https://archives.nida.nih.gov/sites/default/files/podat-3rdEd-508.pdf

BHG holds an active Drug Enforcement Administration ("DEA") license which allows it to administer these narcotics. While Methadone is a Schedule II Narcotic, it is approved by the Federal Drug Administration ("FDA") and widely accepted in the medical community as the safest and most effective medication for treating individuals with OUD.[6] In South Carolina, and across the country, there is a strong push to make MAT using Methadone more accessible to patients suffering from OUD. In fact, the South Carolina State Health Plan promotes the development of more OTPs, and our regulatory bodies are actively eliminating barriers to physicians treating patients with OUD.[7]

Beyond the standards of medical care that govern OTPs, OTPs are unique and highly regulated medical facilities. DHEC Regulation 61-93 promulgates Standards for Licensing Facilities for Chemically Dependent or Addicted Persons ("Regulations").[8] These Regulations guide OTPs, staffing requirements thereof, and various aspects of opioid treatment, e.g., urine drug screening, medication diversion control, etc. Similarly, 42 CFR 8.11 governs Opioid Treatment Program Certification, and 42 CFR 8.12 provides Federal Opioid Treatment Standards governing OTPs.

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[6] https://pubmed.ncbi.nlm.nih.gov/25747920/, "Medication-assisted treatment of opioid use disorder: review of the evidence and future directions"; https://www.samhsa.gov/medications-substance-use-disorders, "Medications for Substance Use Disorders; https://rockinst.org/blog/what-medications-are-used-in-medication-assisted-treatment/, "What Medications Are Used In Medication-Assisted Treatment"

[7] "Due to the increasing number of opioid deaths in South Carolina, additional [OTPs] are needed for the services to be accessible within 30 minutes' travel time for the majority of state residents. The benefits of improved accessibility will outweigh the adverse effects of the duplication of this existing service." 2020 S.C. Health Plan, p. 55.

[8] See D.H.E.C. Reg. 61-93, Standards for Licensing Facilities for Chemically Dependent or Addicted Persons: https://scdhec.gov/sites/default/files/Library/Regulations/R.61-93.pdf

Furthermore, SAMHSA publishes Federal Guidelines for Opioid Treatment Programs, which are frequently updated and often reissued due to the constantly changing climate of the opioid epidemic and the best approaches for OTPs in treating patients using Methadone.[9]

Simply put, treatment standards in OTPs are far more extensive than the baseline standards of medical care governing physicians treating substance abuse in a non-OTP, general behavioral healthcare practices.

APPLICABLE LAW

Expert testimony is characterized by opinions based on facts not within a witness's firsthand knowledge. Admission of expert testimony is governed by Rule 702, F.R.E. The Rule reads as follows:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, may testify thereto in the form of an opinion or otherwise.

Rule 703, FRE. In Daubert, the U.S. Supreme Court made "general observations" on some of the "many factors" that may be relevant to determine the validity of scientific expert testimony. Daubert v. Merrell Dow Pharmaceuticals, 509 U.S. 579, 593 (1993). These observations, commonly referred to as the Daubert factors (or less accurately as the Daubert test) are as follows: (1) whether the theory or technique has been tested or is capable of being tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) the known or potential rate of error; (4) the existence and maintenance of standard and controls; and (5) general acceptance within the scientific community. Id. at 593-94. These factors all bear on the "touchstones of admissibility," reliability and relevance. US v. Crisp, 324 F.3d 261, 268 (4th Cir. 2006).

[9] Federal Guidelines for Opioid Treatment Programs (samhsa.gov)

In Kumho, the U.S. Sup. Ct held that the "general observations" of Daubert may be applied to determine the reliability of non-scientific expert testimony. However, applying all the Daubert factors for all expert testimony, scientific or non-scientific, is not required. While a court may use one or more of the Daubert factors for non-scientific expert testimony, "Daubert's list of specific factors neither necessarily nor exclusively applies to all experts or in every case." 526 U.S. at 141. Two important points flow from this holding. First, the Daubert factors need not be exhaustively applied to every reliability analysis of scientific expert testimony.[10] Second, the Daubert factors are not an exclusive list of considerations to determine expert testimony reliability. See Maryland Cas. Ins. Co. v. Therm-o-Disc, Inc., 137 F.3d 780, 785 (4th Cir. 1998) (rejecting the notion that there are certain factors courts *must* apply to comply with Daubert) (emphasis in original).

Cases from the Fourth Circuit provide some guidance on a definition for "reliability." Courts must determine that the proffered testimony is the "product of reliable principles and methods that are reliably applied to the facts of the case." US v. Wilson, 484 F.3d 267 (4th Cir. 2007) (quoting FRE 702 advisory committee's note). In other words, the testimony must be "supported by adequate validation to render it trustworthy." US v. Moreland, 437 F.3d 424, 431 (4th Cir. 2006). Defining the parameters of reliability for non-scientific expert testimony is "somewhat more opaque" than scientific expert testimony. Wilson, 484 F.3d at 274. The non-scientific expert must "explain how his experience leads to the conclusion reached, why his experience is a sufficient basis for the opinion and how his experience is reliably applied to the facts." Id.

[10] Justice Scalia, joined by Justices O'Connor and Thomas, noted in concurrence that expert testimony reliability analyses lie within the trial court's discretion. Scalia suggested that failure to apply one or more of the Daubert factors in any particular case could constitute an abuse of that discretion. Kumho, 526 U.S. at 158-59 (Scalia, J., concurring).

Despite FRE 702's aim to liberalize the process of admitting expert testimony by removing the absolute requirement of general acceptance, courts recognize that expert witnesses have the potential to be both powerful and misleading. Westberry v. Gislaved Gummi AB, 178 F.3d 257, 261 (4th Cir. 1999).

Since scientific and non-scientific expert testimony can arise in so many different areas of expertise, Daubert and progeny acknowledge that an appropriate reliability analysis can take on a variety of different forms. Therefore, the choice to apply or not apply some or all of the Daubert factors to a particular case is a decision that lies within the trial judge's discretion. Kumho, 526 U.S. at 153.

ARGUMENT

I. Dr. Strahl has not practiced in an OTP in twenty-one (21) years.

Dr. Strahl is a physician certified by the American Board of Psychiatry and Neurology. He treats a variety of behavioral health and psychiatric conditions such as PTSD, schizophrenia, depression, suicidal behavior, bipolar disorder, and substance use disorder. There is no question that Dr. Strahl would be qualified to render standards of care opinions regarding other psychiatrists in many settings.

In this case, Dr. Strahl aims to criticize "the [OTP's] failure to provide adequate treatment to a patient who is abusing opioids." See Ex. 1, Dep. Nathan Strahl, MD, 12:9-10. Per Dr. Strahl, he was hired to perform a "Forensic Psychiatric Assessment regarding treatment provided by BHG, an Opioid Treatment Program (OTP), to Trent Neal. Mr. Neal sought treatment on 6/2/2020 from BHG for treatment of substance abuse." See Ex. 2, Expert Report Nathan Strahl, MD, p. 1. That is another way of saying he was retained by the Richard A. Harpootlian Law Firm to assess if BHG, an OTP, met the Standard of Care for the treatment of Mr. Neal. Id.

Yet, according to Dr. Strahl, he has not worked in an OTP or treated patients with Methadone in *twenty-one (21) years*. Ex. 3, Curriculum Vitae of Nathan Strahl, MD; Ex. 1, Dep. Nathan Strahl, MD at 9:25-10:4. This was at the Raleigh Methadone Treatment Center, up until the year 2002. Twenty-one years ago. When asked about this during his deposition, Dr. Strahl could not even remember the last time he worked in an OTP. Ex. 1, Dep. Strahl, MD at 9:13-15.

There must be a direct connection between Dr. Strahl's knowledge and the opinions he intends to offer. JFJ Toys, Inc. v. Sears Holdings Corp., 237 F. Supp. 3d 311, 322 (D. Md. 2017) (citing Shreve v. Sears, Roebuck & Co., 166 F. Supp. 2d 378, 392 (D. Md. 2001). However, Dr. Strahl does not treat patients with Methadone, the medication that T.N. was prescribed. Dr. Strahl testified in his deposition: "What I can say unequivocally is it's been a substantial amount of time since I prescribed or dealt with methadone . . . there's no question that it's been at least 10 to 15 years." Id. at 9:24-25; 10:1-4. Dr. Strahl treats patients in a generalized behavioral health setting. When he does treat patients suffering from opioid use disorder, he uses Buprenorphine, a medication that T.N. was not prescribed. Id. at 9:25-10:4.

Dr. Strahl has *never* attended a key conference where best practices and standards of care at OTPs are discussed. He has never attended the Governor's Institute for OTP medical providers teleconference— in fact he had never heard of it. Id. at 10:17-23. Dr. Strahl has never attended one of the addiction medicine conferences (in either Asheville or Durham). Id. at 10:24-11:1. Instead, to form the bases for his opinions, Dr. Strahl reviewed a "moderate" amount of literature that including some "updated tips and requirements and the OTP requirements." Id. at 11:6-12. In fact, Dr. Strahl's opinions are "80 percent . . . based on [his] overall knowledge," which, again, has nothing to do with an OTP. Id. at 11:17-19. Regarding the vast state and federal regulations governing OTPs, Dr. Strahl merely "looked at the updated tips and requirements and the OTP

requirements for treatment of patients with – at an OTP." Id. 11:17-19. Dr. Strahl did not list a single piece of medical literature, a specific regulation, or even an OTP conference PowerPoint presentation in his report or deposition.

When Buprenorphine is not working for his patients, Dr. Strahl will often send his patients to the Morse Clinic, an OTP owned and operated by Defendants' expert, Dr. Eric Morse, for more intensive therapy involving appropriate randomized urine drug screening and, potentially, daily trips to the OTP (like T.N. was required to do). Id. at 8:2-11. He does not send them to the hospital or inpatient treatment if they are not acutely impaired or overdosing.

Simply put, Dr. Strahl may treat some patients with OUD, but he is no longer familiar with OTPs and the way they work, or the standards of care and regulations that govern them. Moreover, these standards and regulations have changed dramatically since Dr. Strahl last practiced in an OTP back in 2002— in fact, they are updated almost yearly.

II. Dr. Strahl's opinions are based on unreliable and outdated principles.

However, by Dr. Strahl's own admission, his opinions are "80 percent . . . based on [his] overall knowledge." Id. at 11:17-19. The problem with this is clear— Dr. Strahl's knowledge has nothing to do with OTPs. He practices medicine in a general behavioral health facility. Any opinions Dr. Strahl provides will not be the "product of reliable principles and methods that are reliably applied to the facts of the case." US v. Wilson, 484 F.3d 267 (4th Cir. 2007). His psychiatry board certification is not a license to opine on subject matters that go beyond his area of expertise. See In re Pella Corp., 214 F. Supp. 3d 478, 496 (D.S.C. 2016).

Dr. Strahl must "explain how his experience leads to the conclusion reached, why his experience is a sufficient basis for the opinion and how his experience is reliably applied to the facts." Id. Dr. Strahl has not done so. Instead, Dr. Strahl merely says his opinions are based on

his "overall knowledge" and expects this Court to believe that knowledge is sufficient to render opinions regarding the unique and highly regulated OTP setting. Ex. 1, Dep. Strahl, MD at 11:17-19; Wilson, 484 F.3d at 274. That leap is too far, and this Court should not make it. Dr. Strahl must not be permitted to talk to our jury about OTPs and Methadone maintenance, a topic that goes outside the "reasonable confines" of his practice. Ralston v. Smith & Nephew Richards, Inc., 275 F.3d 965, 970 (10th Cir. 2001).

As the Court reasoned in Kumho, a court need not even doubt an expert's underlying qualifications to find his methodology for reaching conclusions unreliable. Kumho, 119 S.Ct. 1167 at 1176-77 (confirming the lower courts' decision to exclude a witness on the basis that, despite the expert's overall experience, the expert lacked the specialized knowledge needed to assist the jury in deciding the issues in that specific case). Dr. Strahl cannot explain why his knowledge of OTPs from twenty-one (21) years ago is applicable to OTPs today. He did not pull his ideas from peer reviewed literature surrounding OTPs. He did not base his opinions on federal and state regulations. More importantly, Dr. Strahl is not familiar with the current standards governing OTPs, especially since they have dramatically changed over the past few years with the Fentanyl crisis.[11] He certainly did not gather his information from key conferences where best practices and standards of care at OTPs are discussed. See Ex. 1, Dep. Strahl, MD at 10:17-25; 11:1.

[11] According to the CDC, "Fentanyl is a synthetic opioid that is up to 50 times stronger than heroin and 100 times stronger than morphine. It is a major contributor to fatal and nonfatal overdoses in the U.S." See https://www.cdc.gov/stopoverdose/fentanyl/index.html

III. Dr. Strahl's opinions are not supported by peer review or medical literature. Rather, they are in direct conflict with accepted standards in OTPs.

Dr. Strahl's opinions about what *should* have happened with T.N. in an OTP are not based on up-to-date knowledge and peer reviewed information. Ironically, Dr. Strahl's opinions are almost entirely disputed by Dr. Eric Morse, the Defense Expert in this case to whom Dr. Strahl sends his patients when they need advanced OTP care. Ex. 1, Dep. Strahl, MD at 8:2-11; see also Ex. 4, Expert Report Eric Morse, MD. For instance, Dr. Strahl contends that from the time of his admission in June 2020, T.N. should have only been given a "month to a month and a half" to decrease his illicit drug use; and, once T.N.'s benzodiazepine use began, T.N. "should have been referred immediately to an inpatient treatment program because things are getting really bad." Ex. 1, Dep. Strahl, MD at 46:2-9. "It's egregious," says Dr. Strahl, "to have let this go so long . . . they are not providing the structure that's demanded for [T.N.'s] unique case, which is much more severe than the average methadone patient coming in." Id. at 54:8-55:8.

Dr. Strahl's views are universally rejected in the OTP world, and he does not cite a single source in his expert report or deposition to support his theory. Ironically, Dr. Strahl does not send his patients who need more intensive opioid treatment to inpatient services— he sends them to an OTP. Id. at 8:2-11. Conveniently, Dr. Strahl has no idea whether there was a single inpatient facility who would accept a patient like T.N. during the height of Covid-19. Id. at 76:13-18.

In fact, the Substance Abuse and Mental Health Services Administration (SAMHSA), citing the National Institute on Drug Abuse (NIDA), promulgates that "the length of methadone treatment should be *a minimum of 12 months*. Some patients may require long-term maintenance"

(emphasis added).[12] According to the NIDA's 2014 publication "Principles of Drug Addiction Treatment: A Research-Based Guide (Third Edition),

> The appropriate duration for an individual depends on the type and degree of the patient's problems and needs. Research indicates that most addicted individuals need *at least* 3 months in treatment to significantly reduce or stop their drug use and that the best outcomes occur with *longer durations of treatment*. Recovery from drug addiction is a long-term process and frequently requires multiple episodes of treatment.[13] (emphasis added)

Basically, the leading resource on Methadone maintenance treatment at OTPs says you need to give this process time and keep patients in treatment. A lifetime addiction to heroin or opioid pain killers does not disappear overnight. Even if they do disappear within a few months, there is a high likelihood of relapse. Dr. Strahl might refer his patients who need higher levels of care to OTPs, but the literature and regulations are clear that the goal of OTPs is to keep patients engaged in treatment— especially patients like T.N. who have been in treatment for six months or less.

Dr. Strahl's objections to T.N.'s care are no more than boilerplate objections to the treatment rendered to T.N., and he cannot point to anything besides himself for why he has those objections— he categorically dismisses the notion that OTP treatment models might differ from his on general behavioral health practice. See Cooper v. Smith & Nephew, 259 F.3d 194, 201-02 (4th Cir. 2002) (holding a practicing orthopedic surgeon's opinions were unreliable because he had no medical evidence upon which to base his opinions and his opinions were not tailored to the specific case, rather they categorically dismissed any other potential cause of plaintiff's injuries).

Dr. Strahl has given this Court no information (beyond his "experience") as to why his opinions are reliable. Not a piece of medical literature, not an OTP conference PowerPoint—

[12] https://www.samhsa.gov/medications-substance-use-disorders/medications-counseling-related-conditions/methadone
[13] https://archives.nida.nih.gov/sites/default/files/podat-3rdEd-508.pdf

nothing. He has no foundation for saying T.N. was "more severe" than the average patient, a theory that is simply not true. Dr. Strahl's opinions have the potential to be both powerful and misleading to this Court and to our future jury. Westberry v. Gislaved Gummi AB, 178 F.3d 257, 261 (4th Cir. 1999). This Court should exclude Dr. Strahl's testimony.

IV. Dr. Strahl's opinions relate to health care matters that he is legally restricted from performing.

This Court should consider Nelson, a case where our South Carolina Court of Appeals reversed a trial court order and held that a physical therapist lacked the qualifications required to offer a medical causation opinion. Nelson v. Taylor, 553 S.E.2d 488, 491 (S.C. Ct. App. 2001). Nelson recognized that the court's analysis of the therapist's qualifications under state Rule 702 must be guided by South Carolina substantive law restrictions on the health care activities a physical therapist may legally perform. 553 S.E.2d at 490 (finding its qualifications analysis must be "guided by the General Assembly's statutory scheme created to define and regulate the practice of physical therapy"). Dr. Strahl's general behavioral health practice is not legally recognized as an OTP and he cannot legally prescribe Methadone. Methadone used to treat those with an OUD can only be dispensed through a SAMHSA certified OTP, like BHG.[14]

V. Dr. Strahl's opinions are not relevant to T.N. and his treatment at BHG Spartanburg.

Simply put, for expert testimony to be admissible, it must also be relevant to the facts at issue. Daubert, 509 U.S. at 591-92, 113 S.Ct. 2786. The trial judge must "make certain that the expert . . . employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." See Kumho at 152, 119 S.Ct. 1167. Dr. Strahl's

[14] See https://www.samhsa.gov/medications-substance-use-disorders/medications-counseling-related-conditions/methadone

opinions about what he does in a generalized behavioral health clinic, regardless of whether he sometimes treats patients with OUD with Buprenorphine, has no relation to the standards and regulations that are specifically promulgated for OTPs and Methadone maintenance treatment.

CONCLUSION

Dr. Strahl's opinions are not reliable. Defendants respectfully ask this Court to grant Defendant's Motion to Exclude Dr. Strahl as an expert witness.

Respectfully submitted,

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s/ Chance M. Farr

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This the 9th day of August 2023.
Spartanburg, South Carolina